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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/212,367	12/15/1998	DAVID BAUNOCH	98.714	8537

20306 7590 04/17/2002

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EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
1744	24

DATE MAILED: 04/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/212,367	BAUNOCH ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	William H. Beisner	1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 12/3/01; 1/29/02 and 2/6/02.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-6 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03 Dec. 2001 has been entered.

### ***Specification***

2. This application contains an appendix consisting of a computer program listing of more than three hundred (300) lines. In accordance with 37 CFR 1.96(c), a computer program listing contained on more than three hundred (300) lines, must be submitted as a computer program listing appendix on compact disc conforming to the standards set forth in 37 CFR 1.96(c)(2) and must be appropriately referenced in the specification (see 37 CFR 1.77(b)(4)). Accordingly, applicant is required to cancel the computer program listing appearing in the current appendix to the specification, file a computer program listing appendix on compact disc in compliance with 37 CFR 1.96(c), and insert an appropriate reference to the newly added computer program listing appendix on compact disc at the beginning of the specification.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al.(EP 0 508 568).

The reference of Muller et al. discloses an apparatus which is capable of reprocessing a specimen from an infiltrating medium to an aqueous fluid which includes a processing chamber (112); means for regulating flow of fluid (120, 129); means for regulating pressure of the processing chamber (257, 259, 232); means for regulating temperature (117); containers (R1-

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R11) for holding a series of any known processing reagents; and a computer control system (286).

While the specific examples of the system do not include the sequential reprocessing as recited in instant claim 1, the disclosure of Muller et al. discusses a known process that can be performed by the disclosed system. Paraffin treated tissue sections are heated then contacted with xylene (clearant agent), then contacted with ethanol (dehydrant agent) and then contacted with aqueous hydrogen peroxide and saline (aqueous fluid) (See page 8).

In view of this disclosure, it would have been obvious to one of ordinary skill in the art to control the disclosed system of the primary reference so as to perform the known reprocessing by sequential control of reservoirs containing the required reagents to reprocess the samples as suggested by the reference of Muller et al. Regulation of temperature, pressure and flow would have been obvious to one of ordinary skill in the art while providing the required contacting conditions between the tissue sample and reagent while maintaining the contacting efficiency of the system.

With respect to claim 2, the reference of Muller et al. also discloses the use of a rotary valve (129).

7. Claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al.(EP 0 508 568) in view of Kinney et al.(US 4,001,460).

The reference of Muller et al. has been discussed above.

Claims 3-6 further differ by reciting the presence of separately valved infiltrating fluid and the use of purging fluids.

The reference of Kinney et al. discloses an automated processing system which is similar to that of Muller et al. In addition to the reagents suggested by the reference of Muller et al., the reference of Kinney et al. also discloses the use of separately provided paraffin reservoirs (13, 14) (infiltrating fluid) which are separately controlled for flow with respect to the other treating agents and discloses the use of purge clearant (9) and purge dehydrant (10).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of the modified primary reference of Muller et al. such that tissue samples may also be automatically processed as suggested by Kinney et al. for the known and expected result of increasing the versatility of the system of Muller et al. since the system Muller et al. is disclosed as an improved means for accomplishing the sequential, multi-step, controlled processing of a slide surface mounted material. With respect to the purging limitations, it would have been obvious to determine the optimum manner in which to purge the system prior to contacting the specimen with the treating agents.

***Response to Arguments***

8. Applicant's arguments with respect to claims 1-6 have been considered but are moot in view of the new ground(s) of rejection.
  
9. The declaration under 37 CFR 1.132 filed 29 Jan. 2002 is insufficient to overcome the rejection of claims 1-6 based upon the prior art of Kinney et al. (US 4,001,460) in view of either Mathiesen et al.(WO 95/17657) or Didenko et al.(US 6,013,438) as set forth in the last Office action or based upon the prior art of Muller et al.(EP 0 508 568) because:

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It refer(s) only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716.

It states that the claimed subject matter solved a problem that was long standing in the art. However, there is no showing that others of ordinary skill in the art were working on the problem and if so, for how long. In addition, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem. See MPEP § 716.04.

With respect to the allegation of copying, copying is not persuasive of nonobviousness when the copy is not identical to the claimed product, and the other manufacturer had not expended great effort to develop its own solution. The evidence of record fails to establish that the system of Exhibit A is identical to any of the instant claims. Also more than the mere fact of copying is necessary to make that action significant because copying may be attributable to other factors such as a lack of concern for patent property or contempt for the patentees ability to enforce the patent. *Cable Electric Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015, 226 USPQ 881 (Fed. Cir. 1985).

Finally, Applicants' comments and the declaration under 37 CFR 1.132 fail to address the disclosure of Muller et al. which clearly suggests automated reprocessing of a tissue sample.

### *Conclusion*

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on 6:40am-4:10pm; alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



William H. Beisner  
Primary Examiner  
Art Unit 1744

WHB  
March 8, 2002